PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70) 2

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
PSX004wo		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CH99/00289	02/07/1999	02/07/1999
International Patent Classification (IPC) or national classification and IPC A61K31/70		
Applicant SCA LOHNHERSTELLUNGS AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/02/2001	08.10.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Domingues, H Telephone No. +49 89 2399 7810

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CH99/00289

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-10 as originally filed

Claims, No.:

1-14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-14 Yes
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-14 No
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	1-14 yes

2. Citations and explanations
see separate sheet

1. Subject-matter of the application

The application discloses a solid formulation of glucosamine sulphate or a mixed salt thereof that is comprised in an effervescent drinkable preparation. Said preparation should contain the necessary daily dose of glucosamine. It should also comprise carbonate or bicarbonate salts and a fruit acid, preferably, crystalline citric acid, to enhance stability, prevent oxidation and help in the release of the carbon dioxide when the preparation is dissolved in water. Other additives, like colorants and flavors, can also be present in the preparation. According to the description, solid glucosamine sulpahte is rather unstable because it is highly hygroscopic and its amino group oxidises easily. The main advantage of the present invention over the prior art is that it provides a storage-stable drinkable formulation that only needs to be administered once a day since it contains a one-day-dose.

2. Concerning section V

The examination was carried out under the assumption that the priority is valid and was based on the following prior art documents cited in the International Search Report:

D1: PATENT ABSTRACTS OF JAPAN vol. 1999, no. 09, 30 July 1999 (1999-07-30) & JP 011 092385 A (KOYO CHEM. KK,JP), 6 April 1999 (1999-04-06)

D2: US-A-3 683 076 (L. ROVATI (MI,IT)) 8 August 1972 (1972-08-08) cited in the application

D3: US-A-4 642 340 (P. SENIN ET AL. (MI,IT)) 10 February 1987 (1987-02-10) cited in the application

D4: EP-A-0 444 000 (HEALTH MAINTENANCE PROGRAMS INC.,U.S.A.) 28 August 1991 (1991-08-28) cited in the application

i) Inventive Step, Art. 33(3)PCT

Claim 1 is directed to an effervescent preparation of glucosamine sulphate or mixed salts thereof. Document D1 refers to a drinkable preparation of glucosamine salt, like glucosamine hydrochloride, that is stable even in the form of a liquid. The therepeutic and pharmacological properties of glucosamine seem to be preserved in such a preparation since it is said to be useful for the treatment of arthropathy. The described preparation also contains an organic acid that may be hydroxilated and a saccharide.

Document D1 is the closest prior art and the difference between this document and the present application is that in former glucosamine hydrochloride is used whereas in the latter glucosamine sulphate or mixed salts (according to the description, pg. 8, glucosamine KCl or glucosamine HCl) are used. Therefore, the underlying technical problem is to obtain an effervescent (drinkable) preparation of glucosamine sulphate or mixed KCl and HCl salts of said compound. This is achieved by the invention by using said glucosamine compounds, a fruit acid, a carbonate or bicarbonate and other additives according to example 1. Methods for the preparation of glucosamine sulphate are known from the prior art (D2, column 1-3; D4, column 4, line 15-23) and, according to the description, pg. 2, the formation of mixed salts of glucosamine sulphate with sodium and potassium chloride has also been described (see also D3). Furthermore, the oral dosage forms of glucosamine sulphate disclosed in D4 contain the essential components of the effervescent preparation of claim 1: glucosamine sulphate, a fruit acid and a carbonate (see column 8).

In view of the disclosures above, it is the opinion of the examining division that the skilled in the art, when faced with the above mentioned technical problem, would combine the teachings in D1 with those in D2, D3 and D4 and arrive at the solution proposed by the invention without the need of inventive activity. Therefore, inventive step as set out in Art. 33(3)PCT cannot be acknowledge for **claim 1** and the dependant **claims 2-13**. Moreover, since claim 14 is a *product-by-process* claim it also lacks inventive step under Art. 33(3)PCT due to the above cited reasons.